IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

JOSEPH J. DRABICK, M.D., :

No. 1:10-CV-1841

Plaintiff,

Hon, John E. Jones III

V. :

.

KATHLEEN SEBELIUS, Secretary, U.S.
Department of Health and Human Services, and her successors; UNITED STATES
DEPARTMENT OF HEALTH AND
HUMAN SERVICES; NATIONAL

PRACTITIONER DATA BANK, an entity : of and run by the U.S. Department of : Health and Human Services; UNITED :

STATES ARMY, UNITED STATES : ARMY MEDICAL COMMAND; COL. :

DOREEN M. LOUNSBERY, Chief, Quality: Management Division, Directorate of Health:

Policy and Services of the United States
Army, and her successors; LTG ERIC B.
SCHOOMAKER, Surgeon General and

Commander, United States Army, United : States Army Medical Command, and his :

successors;

:

Defendants.

MEMORANDUM

June 26, 2012

THE BACKGROUND OF THIS MEMORANDUM IS AS FOLLOWS:

Presently pending before the Court is the Motion to Dismiss or in the Alternative for Summary Judgment (Doc. 13) of the collective Defendants. By

Order of this Court dated May 14, 2012 the Motion was converted to one for summary judgment. (Doc. 46). The Motion has been fully briefed and is thus ripe for disposition. (Docs. 14, 29, 32). For the reasons fully articulated herein, we will grant the Defendants' Motion in its entirety and enter judgment as a matter of law in favor of the Defendants.

I. PROCEDURAL HISTORY

Plaintiff Joseph J. Drabick, M.D. ("Plaintiff"), initiated the above-captioned action by filing a two-count Complaint on September 1, 2010 (Doc. 1) alleging violations of the Administrative Procedure Act ("APA") and constitutional violations actionable pursuant to 42 U.S.C. § 1983 against Defendants Kathleen Sebelius ("Sebelius"), the United States Department of Health and Human Services ("HHS"), the National Practitioner Data Bank ("NPDB), the United States Army Medical Command ("MEDCOM"), Colonel Doreen M. Lounsbery ("Lounsbery"), and Lieutenant General Eric B. Shoomaker ("Shoomaker").

On January 13, 2011, after receiving extensions from the Court (Docs. 7, 9), the collective Defendants filed the instant Motion to Dismiss or for Summary Judgment. (Doc. 13). In their Motion to Dismiss, the Defendants advanced several arguments regarding both administrative exhaustion and the merits of Plaintiff's claims. (*Id.*). The Motion was fully briefed (Docs. 14, 29, 32), and on July 6, 2011,

this Court issued a Memorandum and Order (Doc. 33) finding that Plaintiff had failed to exhaust his administrative remedies and staying the action pending Plaintiff's application to, and a final determination by, the Army Board for Correction of Military Records ("ABCMR"). (*Id.*). The Plaintiff applied to, and was denied relief by, the ABCMR, and on May 1, 2012, upon consideration of a Status Report (Doc. 41) filed by the Plaintiff advising the Court of the ABCMR's determination, the Court lifted the stay in this matter. (Doc. 42).

The Court thereafter elected to dispose of the instant Motion as one for summary judgment in light of the extensive administrative record and the party's reliance upon record evidence in their respective submissions. On May 14, 2012, the Court issued an Order (Doc. 46) notifying the parties pursuant to *Castle v*. *Cohen*, 840 F.2d 173 (3d Cir. 1988), that the instant Motion is deemed a Motion for Summary Judgment and providing the Defendants with an opportunity to file a statement of facts, and the Plaintiff an opportunity to file a responsive statement, pursuant to Local Rule 56.1. (Doc. 46). The Defendants timely filed a Statement of Material Facts (Doc. 47) on May 24, 2012, and the Plaintiff filed a response on June 13, 2012. (Doc. 48). Accordingly, the Motion is ripe for disposition.

II. STANDARD OF REVIEW

Summary judgment is appropriate if the record establishes "that there is no

genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Initially, the moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The movant meets this burden by pointing to an absence of evidence supporting an essential element as to which the non-moving party will bear the burden of proof at trial. *Id.* at 325. Once the moving party meets its burden, the burden then shifts to the non-moving party to show that there is a genuine issue for trial. Fed. R. Civ. P. 56(e)(2). An issue is "genuine" only if there is a sufficient evidentiary basis for a reasonable jury to find for the non-moving party, and a factual dispute is "material" only if it might affect the outcome of the action under the governing law. *Anderson v. Liberty Lobby*, *Inc.*, 477 U.S. 242, 248-49 (1986).

In opposing summary judgment, the non-moving party "may not rely merely on allegations of denials in its own pleadings; rather, its response must . . . set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2). The non-moving party "cannot rely on unsupported allegations, but must go beyond pleadings and provide some evidence that would show that there exists a genuine issue for trial." *Jones v. United Parcel Serv.*, 214 F.3d 402, 407 (3d Cir. 2000). Arguments made in briefs "are not evidence and cannot by themselves create a

factual dispute sufficient to defeat a summary judgment motion." *Jersey Cent. Power & Light Co. v. Twp. of Lacey*, 772 F.2d 1103, 1109-10 (3d Cir. 1985).

However, the facts and all reasonable inferences drawn therefrom must be viewed in the light most favorable to the non- moving party. *P.N. v. Clementon Bd. of Educ.*, 442 F.3d 848, 852 (3d Cir. 2006).

Summary judgment should not be granted when there is a disagreement about the facts or the proper inferences that a fact finder could draw therefrom. *Peterson v. Lehigh Valley Dist. Council*, 676 F.2d 81, 84 (3d Cir. 1982). Still, "the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; there must be a *genuine* issue of *material* fact to preclude summary judgment." *Anderson*, 477 U.S. at 247-48.

III. STATEMENT OF FACTS

The following facts are derived from the record and viewed in the light most favorable to the Plaintiff in accordance with the standard of review applicable to a motion for summary judgment.

Plaintiff, Dr. Joseph A. Drabick ("Plaintiff"), is a medical doctor who served in the United States Army from July 15, 1980 until his retirement on June 30, 2004, at the rank of Colonel. (Doc. 47, ¶ 1). Plaintiff was assigned to the Walter

Reed Army Medical Center ("WRAMC") as a staff physician in the Hematology-Oncology Clinic in June of 2000. (*Id.* ¶ 2). In 2002, Dr. Peter Tsaknis, a retired Army dentist, was diagnosed with Stage III colorectal cancer, and as a staff physician, Plaintiff was required to verify and approve Dr. Tsaknis' chemotherapy regimen. (*Id.* ¶¶ 3-4).

Captain (Dr.) Jasmine Daniels, Hematology-Oncology fellow and Dr. Tsaknis' treating physician, presented the Plaintiff with chemotherapy orders for approval on March 4, 2002. (*Id.* ¶ 5). The orders provided that Dr. Tsaknis was to receive two (2) types of chemotherapy: 20 mg/m2 of Leucovorin and 425 mg/m2 of Fluorouracil (5-FU). (*Id.* ¶ 6). The orders noted that Dr. Tsaknis' body surface area ("BSA") was 1.96 m2. (*Id.*).

In order to determine a particular patient's correct dosage, chemotherapy base dosages are multiplied against the patient's BSA. (Doc. 47, ¶ 7). Applying this formula, Dr. Tsaknis should have received a total of 40 mg/m2 of Leucovorin (20mg/m2 x 1.96 BSA) and 833 mg/m2 of 5-FU (425 mg/m2 x 1.96 = 833). (*Id.* ¶ 8). The chemotherapy order, however, contained a multiplication error which incorrectly reflected that Dr. Tsaknis was to receive a total of 980 mg/m2 of 5-FU, an amount approximately eighteen percent higher than the correct dosage. (Doc. 47, ¶ 8). Plaintiff admits that he "reviewed the orders and signed them, verifying

that the orders were correct." (Id.; Doc. 48, ¶ 6). Further, he admits that the regimen that he approved "was correct regarding the dosage but contained a multiplication error applying the dosage to the patient's body surface area." (Doc. 48, ¶ 7).

The pharmacologist, Lieutenant Colonel Paula Doulaveris (("LTC Doulaveris") reviewed the orders and checked them against the appropriate regimen for Dr. Tsaknis' form of cancer. (Doc. 47, ¶ 9). LTC Doulaveris noted the multiplication error and brought it to Dr. Daniels' attention, and Dr. Daniels amended the orders to increase the dosage of 5-FU from 425 mg/m2 to 500 mg/m2, instead of reducing the total dosage from 980 mg/m2 to 833 mg/m2. (Id. ¶ 10). On March 23, 2002, approximately one week after beginning the first cycle of chemotherapy, Dr. Tsaknis reported to WRAMC "displaying various symptoms consistent with suffering from 'severe toxicity from adjunctive 5FU.'" (Id. ¶ 12). Dr. Tsaknis' condition deteriorated over the next several days and, on March 28, 2002, he progressed to multiorgan failure and died. (*Id.* ¶ 13-14). His immediate cause of death was recorded as "neutropenic enterocolitis due to [or] as a consequence of colorectal carcinoma." (*Id.* ¶ 14).

Shortly thereafter, WRAMC convened a Hematology-Oncology Quality

Improvement ("QI") team, which examined the circumstances surrounding Dr.

Tsaknis' death and concluded that the standard of care was not met in calculating and administering the appropriate chemotherapy dosage. (*Id.* ¶¶ 15-16). A Risk Management ("RM") team likewise found medical error due to administration of an excessive and incorrect chemotherapy dosage. (*Id.* ¶ 17). On December 9, 2002, the WRAMC Patient Care Assessment Committee ("PCAC") concluded that "[s]tandards of care were not met on the part of the fellow, the attending and two pharmacists." (*Id.* ¶ 18). The PCAC recommended requiring countersignatures on changes to chemotherapy orders, and this new policy was implemented shortly thereafter. (*Id.* ¶¶ 18, 20).

Dr. Tsaknis' family filed an administrative wrongful death claim with the United States Army Claims Service on January 24, 2004. (*Id.* ¶ 21). The family "asserted that WRAMC's 'failure to timely diagnose and treat' Dr. Tsaknis' colon cancer 'led to internal burns caused by chemotherapy which led to neutropenic enterocolitis.'" (*Id.* ¶ 21). Plaintiff notes that this claim did not expressly include his name or specific conduct. (Doc. 48, ¶ 21). On June 30, 2004, Plaintiff retired from active service. (Doc. 47, ¶ 22).

The Tsaknis filed a malpractice suit against WRAMC in the United States

District Court for the District of Columbia on February 14, 2005 claiming,

pursuant to the Federal Tort Claims Act ("FTCA") that Dr. Tsaknis had received

negligent medical care which ultimately caused his death. (*Id.* ¶ 23-24). On April 29, 2005, the hospital's Consultation Case Review Branch ("CCRB") reviewed the claim and found that Dr. Tsaknis had "received an incorrect dosage of the 5FU due to a multiplication mistake which caused confusion with the pharmacist." (*Id.* ¶ 24). CCRB further concluded that the standard of care was not met, but due to insufficient data, could not determine to whom to attribute the overdose. (*Id.*).

The Tsaknis family and the United States settled the malpractice claim for one million dollars in September of 2007 without consultation or discussion with the Plaintiff. (*Id.* ¶ 25). In November of 2007, the Army Litigation Division notified Army Medical Command ("MEDCOM") of the settlement and provided MEDCOM with the entire case file. (*Id.*). Defendant Colonel Doreen Lounsbery ("Lounsbery"), Chief of the MEDCOM Quality Management Division, informed Plaintiff by letter of the settlement and advised that a Special Review Panel "SRP" would convene to evaluate the case and determine whether the standard of care had been met. (*Id.* ¶ 26). Defendant Lounsbery invited Plaintiff to provide, in writing, any additional information for consideration during the review. (*Id.*). Plaintiff, by letter, responsed to Defendant Lounsbery, denying error on his part and stating that the change had occurred after he had signed the orders. (*Id.* ¶ 27).

The SRP convened on December 10, 2008 to review Plaintiff's case and

concluded that while his error was "probably the most understandable," it was an error nonetheless. (*Id.* ¶ 28). The SRP unanimously voted to find that Plaintiff had not met the standard of care in treating Dr. Tsaknis. (*Id.*). The MEDCOM staff judge advocate conducted a legal review of the SRP's determination on March 4, 2009 and, noting that the Plaintiff had "signed off on orders containing a multiplication error which he failed to notice," concluded that the SRP's decision was legally sufficient to support a report of Plaintiff to the National Practitioner Data Bank ("NPDB"). (*Id.* ¶ 29).

On March 26, 2009, the Army Surgeon General ("ASG") approved the SRP's findings after reviewing the case file and determined that an NPDB report was warranted. (*Id.* ¶ 30). On April 2, 2009, the ASG notified Plaintiff of his decision, and on April 28, 2009, Defendant Lounsbery notified Plaintiff by letter that his name had been submitted to the NPDB. (*Id.* ¶¶ 30-31). Defendant Lounsbery advised Plaintiff of the basis for the report and included a copy of the medical malpractice payment report. (*Id.* ¶ 31).

Plaintiff filed a dispute with the NPDB on July 15, 2009. (*Id.* ¶ 32). On August 19, 2009, Plaintiff requested a review of his NPDB report by Defendant HHS. (*Id.*). On September 25, 2009, the NPDB informed Plaintiff that a Dispute Resolution Manager had been assigned to his case and advised him of the limited

scope of HHS review. (*Id.*). Defendant HHS notified Plaintiff on June 23, 2010, that it had denied his request to void the NPDB report. (*Id.* ¶ 33). Plaintiff then filed his Complaint with this Court on September 1, 2010. (Doc. 1). The Court stayed the action pending Plaintiff's application to, and final determination by, the Army Board for Correction of Military Records ("ABCMR"). (Doc. 33).

Thereafter, Plaintiff submitted an application to the ABCMR, alleging that the NPDB report was "unjust" and constituted a lack of due process. (*Id.* ¶ 37). The ABCMR sought an advisory opinion from the Office of the Staff Judge Advocate ("OSJA"), which recommended that Plaintiff's request be denied. (*Id.* ¶¶ 38-39). The opinion concluded that no error or injustice had occurred in the review of Plaintiff's case or the manner of reporting to the NPDB. (*Id.*). The ABCMR, in reliance upon the OSJA opinion and its review of the record, denied the Plaintiff's application on March 29, 2012. (*Id.* ¶ 42). On May 1, 2012, upon advisement of the ABCMR's decision, this Court lifted the stay in this matter.

IV. DISCUSSION

In his two-count Complaint, Plaintiff charges the Defendants with violation of the Administrative Procedure Act ("APA") and violations of 42 U.S.C. § 1983 for failing to follow the directives of the Health Care Quality Improvement Act of 1986 ("HCQIA"), 42 U.S.C. § 11101 et seq., in reporting him to the National

Practitioner Data Bank ("NPDB"). We address Plaintiff's § 1983 claims first.

A. Plaintiff's § 1983 Claims

Plaintiff asserts § 1983 claims against all named Defendants, including both agencies and individuals. For the reasons that follow, we will grant judgment as a matter of law to both the agency defendants and the individual defendants on Plaintiff's § 1983 claims.

1. § 1983 and the Agency Defendants

The Defendants argue—and the Plaintiff, in his failure to contest the point, seemingly concedes—that even if this Court were to construe Plaintiff's § 1983 claims against the Defendants as a *Bivens* action, the claims will nonetheless fail as to the agency Defendants because *Bivens* does not provide a right of action against a federal agency. (Doc. 14, pp. 18-19). The Defendants argue that the Plaintiff's claims must be dismissed pursuant to Rule 12(b)(6) to the extent that they allege violations of § 1983 by the agency Defendants, as the Supreme Court has expressly declined such an extension of *Bivens*. We agree.

The Supreme Court in *Bivens* permitted a § 1983 cause of action against a federal *officer* in his individual capacity. *See Bivens v. Six Unknown Named Agents of the Fed. Bureau of Narcotics*, 403 U.S. 388, 389-90 (1971). However, the Court has explicitly announced that "[a]n extension of *Bivens* to agencies of the federal

government is not supported by the logic of *Bivens* itself." *Fed. Deposit Ins. Co. v. Meyer*, 510 U.S. 471, 484 (1994); *see Corr. Servs. Corp. v. Malesko*, 534 U.S. 61, 71 (2001) (holding that *Bivens* creates a private cause of action only against federal officers, not the United States or its agencies); *see also Lomax v. U.S. Senate Armed Forces Serv. Comm.*, 454 Fed. Appx. 93, 95 n.1 (3d Cir. 2011) (Third Circuit stating, in a nonprecedential opinion, that *Bivens* "allows a plaintiff to bring a claim against federal officers acting under color of law for violations of that individual's constitutional rights . . . [h]owever, *Bivens* claims do not lie against the federal government or federal agencies").

Accordingly, absent any contradictory authority or argument from the Plaintiff, we agree with the Defendants' application of *Meyer* and its progeny and find that the Plaintiff is barred from stating a § 1983 claim against the Defendant Agencies, including the United States Department of Health and Human Services, the National Practitioner Data Bank, and the United States Army, Army Medical Command. We will thus grant summary judgment in favor of the agency defendants on Count II.

2. Plaintiff's *Bivens* Claim Against the Individual Defendants

Having dismissed Plaintiff's § 1983 claims against the federal agencies, we proceed to determining whether Plaintiff has stated an appropriate *Bivens* claim

against Defendants Sebelius, Lounsbery, and Schoomaker. The analysis of a *Bivens* claim largely mirrors that of a § 1983 claim, requiring the Court to determine whether the plaintiff has demonstrated (1) a deprivation of a right secured by the Constitution or other laws of the United States and (2) that the deprivation of the right was caused by actions or inactions of an official acting under color of federal law. *See Abuhouran v. Nicklin*, 2012 U.S. Dist. LEXIS 26329, *10-11 (D.N.J. Feb 29, 2012).

Potential *Bivens* actions, however, are further tempered by the Supreme Court's admonishment that the judiciary must exercise its *Bivens* hand with caution and, as a threshold matter, determine *Bivens* justiciability questions prior to reaching the merits of the constitutional claims. *See Wilkie v. Robbins*, 551 U.S. 537, 550 (2007). Indeed, the Supreme Court held, and this Circuit has followed, that *Bivens* actions are defeated where Congress has provided some alternative remedy as a substitute to recovery or where the defendants are able to argue that special factors warrant dismissal of the suit. *See Gaj v. U.S. Postal Serv.*, 800 F.2d 64, 67 (3d Cir. 1986). Under the first prong, the Court should refrain from hearing a *Bivens* action where Congress has "provided an alternative remedy which it explicitly declared to be a *substitute* for recovery directly under the constitution and viewed as equally effective." *Carlson v. Green*, 446 U.S. 14, 19 (1980)

(quoting Bivens, 403 U.S. at 397).

Under the second prong, if the defendant is able to demonstrate "special factors counseling hesitation," the court is encouraged to refrain from permitting the plaintiff prosecute the *Bivens* action. *See Gaj*, 800 F.2d at 67. This ruling has resulted in a vast and ever-expanding array of "special factors," including actions by federal employees against their federal coworker and suits based on military service injuries, to name a few. *See Bush v. Lucas*, 462 U.S. 367, 368 (1983) (federal employee may not bring *Bivens* action against coworker); *Feres v. United States*, 340 U.S. 135, 146 (1950) (no government liability for service injury).

It is upon consideration of this latter category that the Plaintiff's case turns. The Supreme Court in *Feres* held that a serviceman is not able to recover from the federal government under the FTCA "where the injuries arise out of or are in the course of activity incident to service." *Id.* at 145-46. The Supreme Court has extended this longstanding principle to *Bivens* claims, holding that it is equally applicable thereto, with its announcement in *United States v. Stanley*, 483 U.S. 669 (1987) that "no *Bivens* remedy is available for injuries that 'arise out of or are in the course of activity incident to service." *Id.* at 684-85.

The Defendants contend that the injury here, if any there may be, arose out of or in the course of the Plaintiff's military service and the Plaintiff is thus *Feres*-

barred from bringing a *Bivens* claim. Specifically, they assert that the alleged medical negligence giving rise to the lawsuit, settlement, and, ultimately, their report of Plaintiff to the NPDB began with Plaintiff's violation of the applicable standard of care in signing off on inaccurate chemotherapy regimen orders and that the alleged harm, if any there may be, arose from the Plaintiff's employment as an Army medical doctor.

Plaintiff cites to several cases in support of his argument that his injury does not arise out of his service. In *United States v. Brown*, 348 U.S. 110 (1954), the plaintiff suffered an injury to his knee while on active duty. Seven years after his honorable discharge, he underwent a follow-up operation at a military hospital. *Id.* at 110-11. A defective tourniquet used during that procedure worsened that plaintiff's injury. *Id.* The Court relied on *Feres* and found that "[s]ince the negligent act giving rise to the injury in the present case was not incident to the military service," the *Feres* bar was inapplicable. *Id.* at 112.

Plaintiff also points to the Third Circuit's decision in *Valn v. United States*, 708 F.2d 116 (3d Cir. 1983). Valn was discharged from military duty in July of 1974 for medical reasons but received orders to report in September of 1974 for nineteen(19) weeks of training, despite having been discharged. *Id.* at 118. Valn reported for this training, but refused to follow orders; he asserted, unsuccessfully,

that he had no further legal responsibility to the military. *Id.* Sometime thereafter, Valn "was confined and subjected to court martial proceedings" for his refusal, after which a JAG investigation resulted in his release and honorable discharge. *Id.* Valn brought a claim against the United States under the FTCA, alleging negligence in ordering Valn to return to active duty. *Id.* The Third Circuit held that because the harm to Valn arose subsequent to his initial medical discharge, his claim was not barred by *Feres. Id.* at 119.

The Defendants respond by pointing to several cases where courts have found an action to be *Feres*-barred even though the alleged harm was slightly attenuated from the plaintiff's service. In *Richards v. United States*, 1 F. Supp. 2d 498 (D. V.I. Mar. 27, 1988), the court barred the plaintiff from suit where he was an off-duty active serviceman traveling home in his personal vehicle when, on a public road, he was struck by a military vehicle. *Id.* In *Matreale v. N.J. Dep't of Military & Veterans Affairs*, 418 F. Supp. 2d 603 (D.N.J. Mar. 8, 2006), the Court found that a suit by an active-duty officer against the New Jersey Army National Guard alleging disciplinary retaliation against him for his participation in a sexual harassment suit against it was also prohibited by *Feres*. Similarly, in *Fanslau v. 177th Fighter Wing of Air Nat'l Guard of N.J.*, 2006 U.S. Dist. LEXIS 43993 (D.N.J. June 28, 2006), another case brought by an active-duty officer alleging

retaliation by his superiors, the court found the claim to be *Feres*-barred.

We believe that the Plaintiff's reliance on *Brown* and *Valn* is misplaced. In both *Brown* and *Valn*, the particular claims at issue arose from incidents outside of and distinct and extricable from each plaintiff's military service. Indeed, actions of others, independent from the plaintiff's military service, were superseding events giving rise to the causes of action. In this Court's view, *Matreale* and *Fanslau*, cited by the Defendants, are far more analogous to the case *sub judice*. Like *Matreale* and *Fanslau*, the harm suffered by the Plaintiff here arose from events occurring while the Plaintiff was practicing at WRAMC, when he allegedly committed medical negligence and the Defendants failed to notify him of the *Tsaknis* litigation to which he was not a party but which was, at least in part, premised upon his treatment of Tsaknis.

In sum, it is clear to this Court that the nature of the Plaintiff's military service was the practice of medicine at the WRAMC, and the basis of his alleged harm stems from negligent actions committed during that service. Thus, any injury alleged which arises from the Plaintiff's practice of medicine at the WRAMC necessarily "arise[s] from his military service." Accordingly, we find that the Plaintiff's § 1983 claims are *Feres*-barred and will grant summary judgment to the Defendants on Count II.

B. Plaintiff's APA Claims

Plaintiff asserts APA violations against Defendants Army MEDCOM,
Lounsbery, and Schoomaker (collectively, "Army Defendants"), contending that
their report of the Plaintiff to the NPDB was in error both factually and
procedurally, and against Defendants Sebelius, HHS, NPDB (collectively, "HHS
Defendants"), asserting that HHS should have remedied the erroneous report upon
review of the Plaintiff's claim. He argues that both groups have, collectively and
individually, reported him to the NPDB in a manner that was arbitrary, capricious,
an abuse of discretion, or otherwise not in accordance with the law in violation of
the APA. (Doc. 1, ¶ 37-38). We disagree and conclude that ample evidence
supports the Army Defendants' decision to report the Plaintiff to the NPDB and the
HHS Defendants' decision not to reverse or void the report.

1. Army Defendants

Plaintiff first contends that the Army Defendants, in failing to notify him of the *Tsaknis* litigation, violated the APA by acting in a manner contrary to law, namely, Federal Rule of Civil Procedure 4(i)(2), which requires that a complaint served upon the United States must also be served upon the federal employee whose conduct was at issue. *See* Fed. R. Civ. P. 4(i)(2). However, the Plaintiff himself admits that he was not a named defendant in the lawsuit, and thus the

failure to notify him of the litigation is not in conflict with Rule 4(i)(2). We cannot find that the Army Defendants' failure to provide notice to the Plaintiff of a lawsuit in which he was not a party-defendant and in which the party-plaintiffs did not expressly name him or his conduct to have been arbitrary, capricious, an abuse of discretion, or contrary to law.

Plaintiff next submits that, because the *Tsaknis* plaintiff did not name him as a defendant or specifically criticize his care, the Army Defendants acted contrary to law by reporting him to the NPDB. Plaintiff contends that because the plaintiff in the underlying medical malpractice action did not specifically identify him in the complaint, the Army Defendants' decision to report him to the NPDB following their internal investigation of Tsaknis' treatment was in error. We find that this argument, too, is without merit, and conclude that there was nothing arbitrary or capricious about the Army Defendants' decision to report the Plaintiff to the NPDB following their investigation.

As the Defendants' comprehensive discussion of the Health Care Quality Improvement Act ("HCQIA"), 42 U.S.C. § 11101 et seq., explains, Congress enacted the statute in order to improve the quality of medical care and decrease medical malpractice nationwide. H.R. Rep. No. 99-903, 2-3. A major facet of the HCQIA was the creation of the National Practitioner Data Bank ("NPDB), which

collects and disseminates reports of practitioner competency, malpractice, and conduct. Medical malpractice insurers, state medical licensing boards, hospitals, and other entities are required by the HCQIA's terms to report instances of medical negligence to the NPDB. 42 U.S.C. §§ 11131-34. The HCQIA did not, by its terms, mandate application of its reporting requirements to federal health care entities such as the Department of Defense ("DOD"). However, Congress desired DOD participation and encouraged it by including language in the HCQIA which suggested HHS enter into a memorandum of understanding ("MOU") with DOD applying the HCQIA to military medical staff and entities. *Id.* § 11152.

HHS and DOD, following Congress's suggestion, signed an MOU outlining DOD reporting protocols in September of 1987. The regulations promulgated to implement the MOU provide for an independent review of medical malpractice cases in which the entity or its insurer make settlement payments. See Army Reg.

¹ Plaintiff contends in his brief in opposition that the MOU between the DOD and HHS is inconsistent with the Congressional intent in enacting the HCQIA. We find this argument to be without merit but nonetheless address it briefly in fairness to the Plaintiff. The HCQIA, by its own terms, does not apply to federal health care providers. 52 Fed. Reg. 42722 (Oct. 17, 1989). Desiring federal health care entities participation in the malpractice database, Congress suggested HHS enter into a memorandum of understanding ("MOU") with the DOD implementing HCQIA as between the DOD and HHS. *See* 42 U.S.C. § 11152. The DOD and HHS entered into an MOU, the language of which Plaintiff now, for the first time, asserts is inconsistent with the Congressional directive. The MOU provides that "[a] report shall be filed with the [NPDB] . . . on any payment of a malpractice claim against the DoD, an Agency of the DoD, or a health care practitioner working for the DoD. In accordance with DoD policy, all malpractice claims shall be analyzed by peer review, assigned a category of responsibility, and reported" pursuant to a hierarchy of deviation from the standard of care. (Ex. 4). Plaintiff points

40-68 (Feb. 26, 2004). These regulations provide first for a peer review process where a physician uninvolved in the subject treatment issues both standard of care and attribution determinations. *Id.* ¶ 13-5(b)(3). After peer review is completed and standard of care and attribution determinations are made, a MEDCOM Special Review Panel ("SRP") evaluates the case to determine whether the applicable standard of care was satisfied. *Id.* ¶ 13-6(f)(3). The SRP affords the subject physician an opportunity to submit information on his or her behalf and then reviews the entire case file to make a final determination with regard to whether to report physicians significantly involved in the treatment of the underlying patient. *Id.* ¶ 13-6(g)(2). The SRP then renders a final standard of care determination and, if a deviation is found, the physician is reported to the NPDB. *Id.*

The facts demonstrate to this Court that this procedure was thoroughly complied with by the Army Defendants in the instant action. Immediately after Dr. Tsaknis' death and prior to the underlying medical negligence action being filed, WRAMC engaged in thorough review of the circumstances surrounding his demise. The WRAMC's Quality Improvement team immediately convened and

to no authority supporting his contention that this Congressionally-approved MOU, requiring independent investigation of all settled medical malpractice claims in substantial similarity to the exact language of the HCQIA, is in fact inconsistent with Congress's intent in enacting HCQIA. We thus decline to conclude, as Plaintiff apparently would have us, that the MOU is invalid as being contrary to Congressional intent.

found that the standard of care was not met due to the incorrect chemotherapy dosage. (Doc. 47, ¶¶ 15-16). A Risk Management team reviewed and agreed with this report. (*Id.* ¶ 17). After completing its own review, the WRAMC's Patient Care Assessment Committee concluded that the standard of care was not met and recommended amending standard operating procedure to require countersignatures in order to avoid similar errors in the future. (*Id.* ¶ 18).

When the underlying malpractice lawsuit was filed, the Consultation Case Review Branch ("CCRB") reviewed the claim, concluding that an incorrect chemotherapy dosage had occurred as a result of Plaintiff's multiplication mistake. (*Id.* ¶ 24). In September of 2007, when the underlying claim settled, pursuant to the MOU, the Army Litigation Division notified MEDCOM of the settlement and forwarded the case file for review. (*Id.* ¶ 25). Defendant Lounsbery the Plaintiff of pending SRP review and provided him the opportunity to submit information in his defense, which he did. (*Id.* ¶ 26). Plaintiff was advised that a potential outcome of the review could be a report to the NPDB. (*Id.*).

The SRP convened to review the record, including Plaintiff's response letter in which he denied allegations of medical error, and determined that while his was "probably the most understandable" error, it was error nonetheless. (*Id.* ¶ 28). The SRP unanimously concluded that Plaintiff failed to meet the applicable standard of

care. (*Id.*). An Army MEDCOM staff judge advocate ("JAG") conducted a review of the SRP's findings on March 4, 2009, and found it legally sufficient to support a NPDB report. (*Id.* ¶ 29). After reviewing the evidence, the Army Surgeon General approved the SRP findings on March 26, 2009, and concluded that an NPDB report was required. (*Id.* ¶ 30).

The Plaintiff does not deny that he was significantly involved in Dr.

Tsaknis' medical treatment and that he reviewed and approved the erroneous chemotherapy dosage. He does not contest that the orders, due to a multiplication error, resulted in Dr. Tsaknis' receiving an amount of 5-FU eighteen percent (18%) higher than the correct dosage. Instead, Plaintiff contests the "manner" in which the Army Defendants' reported him to the NPDB. Our above review of the Army Defendants' procedural handling of the review and ultimate report of the Plaintiff demonstrates that the Army Defendants acted appropriately and in accordance with governing law and regulations in reporting Plaintiff to the NPDB.

Finally, we disagree with Plaintiff's contention that the Army Defendants' decision to report him lacked factual support. As above-stated, Plaintiff admits that he committed medical error. Thus, he has entirely failed to demonstrate that any of the several medical review panels made arbitrary or capricious factual determinations. Thus, we cannot find on the record before us that genuine issues of

material fact exist with respect to whether the Army Defendants' procedural and factual determinations in reporting the Plaintiff to the NPDB were arbitrary, capricious, or contrary to law. We will accordingly grant summary judgment to the Army Defendants on Count I.

2. HHS Defendants

Defendant HHS has procedures in place which allow a physician who disputes the accuracy of a report to air his grievances and obtain review from the Defendant Secretary. 45 C.F.R. § 60.14. Plaintiff charges that the HHS Defendants have violated the APA because "[the] HHS [Defendants] should have removed his name from the NPDB because he was not properly reported pursuant to the statutory reporting requirements." (Doc. 29, p. 30). He asserts that the HHS Defendants acted arbitrarily, capriciously, and contrary to law in failing to void the report upon learning that the Army Defendants had not followed proper reporting requirements.

Notably, we have hereinabove concluded that the Army Defendants in fact exceeded the review efforts required of them and properly abided by the NPDB reporting requirements and that there is thus no merit to Plaintiff's claim to the contrary. We cannot find, then, as a matter of law, that the HHS Defendants' decision not to void appropriately-reported records was arbitrary, capricious, an

abuse of discretion, or contrary to law. Accordingly, we find that Plaintiff has not presented the Court with any genuine issues of material fact for trial with respect to his APA claim against the HHS Defendants and will grant judgment to the HHS Defendants on Count II.

V. CONCLUSION

For all of the foregoing reasons, we will grant the Defendants' Motion to Dismiss or in the Alternative for Summary Judgment (Doc. 13), converted to a Motion for Summary Judgment by this Court's Order dated May 14, 2012, (Doc. 46), in its entirety and enter judgment as a matter of law in favor of the Defendants on all claims in the Plaintiff's Complaint. An appropriate Order shall issue.